

# United States Senate

WASHINGTON, DC 20510

May 15, 2017

The Honorable Mick Mulvaney  
Director  
The White House Office of Management and Budget  
725 17<sup>th</sup> Street, NW  
Washington, DC 20503

Dear Director Mulvaney:

According to media reports, you said on Thursday that you have been actively discussing potential executive or administrative solutions with the President to address rising prescription drug costs. Similarly, Secretary Price has been holding “listening sessions” to discuss possible solutions. We write to express our support for such efforts that could provide immediate relief to Americans.

We have worked together on bipartisan legislation that would address skyrocketing drug prices, including bills to allow for personal importation of medications from Canada, where drug prices are, on average, half the cost they are in the United States, and bills that would deter pharmaceutical companies from blocking cheaper generic alternatives from entering the marketplace.

While we pursue these legislative options in Congress, we strongly encourage you to take executive or administrative action to reduce the ever-increasing financial burden of prescription drugs for millions of Americans. We have previously outlined ways that the Administration could implement such strategies in a targeted manner that satisfies rigorous safety standards.

Specifically, we wrote to Secretary Price in February urging him to utilize authority the Administration already has under law. Our letter highlighted that Congress enacted legislation in 2003 that would enable importation of less costly medications from abroad. Under this law, the Food and Drug Administration (FDA) can permit pharmacists and wholesale retailers to import prescription drugs from Canada. Additionally, the FDA can issue a waiver to allow individuals to import prescription drugs for personal use. However, this law stipulates that the provisions related to importation do not become effective until the Secretary of Health and Human Services certifies that the implementation of importation would pose no additional risk to the public's health and safety and would result in a significant reduction in the cost of covered products to the American consumer.

Consistent with your comments last week, the Administration has an opportunity to use existing statutory authority to quickly restore competition to the market with the introduction of cheaper,

imported alternatives. Under the statute, the Secretary has the authority to issue the certification in a targeted manner to address the current market conditions in a way that readily meets safety standards. The policy can also be expressly limited so that it does not negatively affect innovator companies that invested in the development of the drug.

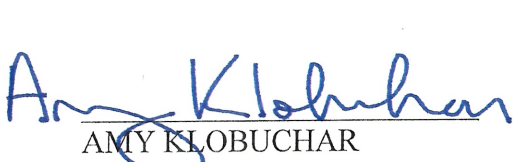
We urge you to work with Secretary Price to immediately begin considering certifying importation of prescription drugs from Canada in the following circumstances:

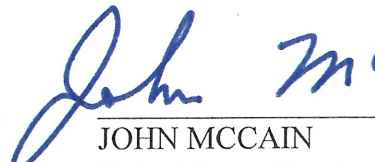
1. The drug is off patent or no longer marketed in the United States by the innovator company that initially developed the drug;
2. In cases where there are significant and unexplained increases in price;
3. No direct competitor drug is currently in the market and introduction of a competitor drug will benefit the prices paid by taxpayers and consumers; or
4. The drug is produced in another country by the name brand manufacturer that initially developed the drug or by a well-known generic manufacturer that commonly sells pharmaceutical products in the United States.

We urge you to seriously consider this existing statutory authority as well as explore other options for executive action. We also ask that you please provide your recommendations as to what additional authority you would require to protect American consumers. Of course, we would welcome your support of our legislation to bring down the costs of prescription drugs as well.

We look forward to your timely response to this request.

Sincerely,

  
AMY KLOBUCHAR  
United States Senator

  
JOHN MCCAIN  
United States Senator

  
CHARLES GRASSLEY  
United States Senator

Cc: Secretary Tom Price, U.S. Department of Health and Human Services